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EXAMINER				
PALENIK, JEFFREY T				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,811

Applicant(s)

JUGLA, LUC

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Receipt is acknowledged of Applicants' Amendments and Remarks filed 28 May 2008.
The Examiner acknowledges the following:

Claims 9-15 have been amended. Support for the amendments, while not expressly provided, was easily found either within Applicants' disclosure and/or originally filed claims.

No additional claims have been added and no further claims have been cancelled.

Thus, claims 9-16 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objection to the Specification

Applicants' amendments to both the Title and Abstract of the Invention render the objections to the Specification moot. Thus, said objections have been **withdrawn**.

Rejection under 35 USC 112

Applicants' remarks to claim 9 regarding the "phase inversion temperature" render the rejection to claim 9 under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

Applicants' amendment to claim 9 whereby the term "effective" has been removed renders the rejection to claim 9 under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

Applicants' amendment and remarks to claim 10 regarding the lack of antecedent basis for "step c" renders the rejection to claim 10 under 35 USC 112, second paragraph, moot. Thus, said rejection has been **withdrawn**.

Applicants' remarks to claim 12 regarding the term "some" render the rejection to claim 12 under 35 USC 112, second paragraph, moot. Herein, and for the purposes of examination on the merits, per Applicants' remarks, the term "some" with regards to the amount of aqueous phase removed, will be interpreted broadly by the Examiner as reciting "any amount". The rejection is **withdrawn**.

Applicants' remarks to claims 13 and 14 regarding the phrase "an additional amount" render the rejection to claims 13 and 14 under 35 USC 112, second paragraph, moot. Herein, and for the purposes of examination on the merits, per Applicants' remarks, the term "an additional amount" with regards to the amount of aqueous or fatty phase added or used, will be interpreted broadly by the Examiner as reciting "any amount" of the respective phase. The rejection is **withdrawn**.

Rejection under 35 USC 102(b)

Applicants' remarks to claims 9 render the rejection to claims 9-15 under 35 USC 102(b), moot. Thus, said rejection has been **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Action dated 28 January 2008:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "liposoluble phase" in claim 9 is a relative term which renders the claim indefinite. The term "liposoluble phase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As a result, the limitation of "fatty phase" in claim 9, is rendered indefinite as its degree of differentiation from the term "liposoluble phase" is not clear.

RESPONSE TO ARGUMENTS

Applicants' remarks with regard to the above rejection to claim 9 under 35 USC 112, second paragraph, as being indefinite have been fully considered, but is not persuasive.

Applicants remark that claim 9 has been amended replacing the term "liposoluble phase" with "emulsion" as a means of clarifying the claimed subject matter.

In response, the Examiner respectfully disagrees and submits that, in addition to providing no support or evidence for the amendment, the Examiner fails to see how replacing the narrower term "liposoluble phase" with a broader term "emulsion" clarifies the subject matter.

Thus, for these reasons, Applicants' amendment and remark regarding the claim are found unpersuasive. The above rejection is hereby maintained.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Allard et al. (US Patent 5,756,110).

It should be noted that claim 16, despite citing dependence from claim 9 is deemed a product-by-process claim due to the limitation, “that may be obtained via a process as claimed in claim 9” and as such, determination of patentability is based on the product itself, not by the method in which it is made. If the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (MPEP 2113). Claim 16 does not further limit the method itself, but instead claims emulsion-produced nanocapsules averaging less than 300 nanometers (nm) in size (i.e. diameter). Allard et al. teaches at claim 16 that at least 90% of the globules produced from the emulsion resulting from claim 1, have a particle size ranging from 100 nm to 500 nm.

Therefore each of the limitations is met by the reference.

RESPONSE TO ARGUMENTS

Applicants' argument with regard to the rejection of claims 9, 11 and 14-16 under 35 USC 102(b) as being anticipated by Allard et al., has been fully considered and is partially persuasive, but only with regards to claims 9-15. However, regarding claim 16, Applicants' arguments are **not persuasive**.

Applicants argue that because Allard does not anticipate claim 9 that claims 11 and 14-16 which variously depend from claim 9 are also not anticipated.

In response, the Examiner respectfully submits that Applicants' response regarding claims 9, 11, 14 and 15, is correct. However, regarding claim 16, as set forth in the above rejection, claim 16 is interpreted as a product-by-process claim. That is to say the claim is interpreted by the Examiner as an independent composition claim which recites an emulsion which is obtained by a given process. Per MPEP §2113, "even though product-by-process claims are limited and defined by the process [i.e. the method of claim 9], determination of patentability is based on the product itself." Since claim 16 recites an emulsion and the invention to Allard et al. teaches the preparation of emulsions, Allard anticipates claim 16.

Thus, for these reasons, Applicants' arguments are found unpersuasive. The above rejection to claim 16 alone is hereby maintained.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allard et al. (U.S. Patent 5,756,110).

The [bracketed verbiage] recited below is taken from the **withdrawn** 102(b) rejection and imported here for Applicants' convenience. Said material is referred to by the following maintained 103(a) rejection.

[Claim 9 is drawn to a process to encapsulate a liposoluble active principle through preparation of an emulsion wherein the aqueous and fatty phases provided are first heated above the phase inversion temperature (PIT), then mixed together. The resulting emulsion is mixed with the liposoluble active principle, the emulsion temperature is lowered to the phase inversion temperature and then further annealed (i.e. cooled) below the PIT. Claim 11 further limits the method by reversing steps b) and c) in claim 9: rather than separately heating the fatty and aqueous phases prior to mixing them, the two phases are mixed together and then heated. Allard et al. teaches in claim 1 that the method comprises of emulsifying a fatty and aqueous phase at a temperature above the PIT of the medium and then cooling the established emulsion to below the

PIT. It is further taught that an inorganic nanopigment is encapsulated within the emulsion either during the initial emulsification and or after cooling below the PIT. Claims 7 and 8 further define the nanopigment particulates as metal oxides (i.e. iron oxide). The instant claim 14 further limits the method of claim 9 by presenting the active principle for incorporation in to the system (e.g. the emulsion) already dissolved in the fatty phase. Claim 15 further limits the active principle to include liposoluble vitamins, polyphenols and fragrance components. Allard et al. teaches that the fatty phase can contain one or more traditional lipophilic adjuvants such as those incorporated into sunscreen compositions (col. 4, lines 47-50). Cosmetic lipophilic adjuvants that are taught include vitamins and perfumes (col. 5, lines 1-10).]

Allard is taught above (emphasis added), but does not specifically teach the method to include: 1) incorporation of the active principle at a temperature immediately above the phase inversion temperature (claim 10), 2) concentration of the emulsion by withdrawal of some of the aqueous phase (claim 12), or 3) reduction of the emulsion temperature to the phase inversion temperature by adding an additional quantity of aqueous phase cooled to a temperature below the phase inversion temperature (claim 13). However, it is the Examiner's position that adjustment of the concentration of a formulation (i.e. an emulsion) by removal of aqueous material is well known in the art, as shown by Allard et al. which teaches that the aqueous phase of the sunscreen/cosmetic formulation may vary from 50-90% by weight, relative to the total formulation (col. 5, lines 18-24). Furthermore, a case of *prima facie* obviousness is upheld, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). As to the method limitations cited in claims 10 and 13,

the Examiner holds the position that there is no patentable distinction between Applicant's methods and the methods of the prior art. The selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) Selection of any order of mixing ingredients is also held to be *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (see MPEP 2144.04 (IV)(C.))

Additionally, the purpose of Applicant's claimed invention is to supply a process to package pharmaceutical and/or cosmetic active agents which comprises of encapsulation within a PIT emulsion. The same problem and concern is addressed by the Allard reference. Allard teaches the same method which comprises of encapsulation of metal oxides that are formulated into a sunscreen cosmetic formulation (claim 1). Therefore, absent any evidence to the contrary, Applicant's claimed invention achieves the same goal as that of the prior art, with no unexpected results. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 9-16 under 103 over Allard et al. have been fully considered but they are not persuasive.

Applicant alleges that since Allard does not teach or suggest all the claimed features of claim 9, and that claim 9, dependent claims 10-15, and independent composition claim 16, would not have been rendered obvious by the teachings of Allard. Regarding the rejection to claim 9, Applicants' key and only argument against claim 9 is that Allard does not expressly teach the

introduction of the nanopigments into the emulsion after the formation of the emulsion and at a time when said emulsion is still at a temperature above the phase inversion temperature.

In response, the Examiner respectfully submits, as discussed in the teachings to Allard, an emulsion is formed which incorporates a liposoluble active principle into its formulation and then cooled to the phase inversion temperature. The Examiner concedes that the addition of the liposoluble active principle is neither expressly taught as occurring after the emulsion is formed nor at a time when said emulsion is just above the phase inversion temperature. However, a case of *prima facie* obviousness still exists for the reasons already made of record, notably the aforementioned case law directed to *In re Burhans* and *In re Gibson*. Applicants have not provided any evidence emphasizing the criticality of the chronology of the instantly claimed steps.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained.

All claims under consideration remain rejected; no claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.